

Remarks

The specification has been amended to correct the margins in compliance with PTO rules. More particularly, pages 842 to 870 have been deleted from the specification and the subsequent pages have been renumbered accordingly. These pages were inadvertently added to the specification through a clerical error. This amendment is fully supported by the specification and claims as originally filed, and thus no new matter has been added.

Pursuant to 37 C.F.R. § 1.125(b)(2), clearly-labeled marked up pages showing the changes (crossed-out pages 842 to 870) to the originally filed specification is enclosed herewith. Applicants submit that the Substitute Specification as amended fully complies with 37 C.F.R. § 1.52.

Conclusion

Entry and consideration of the above amendment and remarks is respectfully solicited. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425.

Respectfully submitted,

Dated: November 13, 2001


Kenley K. Hoover Reg. No. 40,302
Attorney for Applicants

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9410 Key West Avenue
Rockville, Maryland 20850
301-610-5771 (telephone)

**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL**

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description at Table 6.

B. IDENTIFICATION OF DEPOSIT

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Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)

10801 University Boulevard

Manassas, Virginia 20110-2209

United States of America

Date of deposit

May 20, 1997

Accession Number

209059

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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E. SEPARATE FURNISHING OF INDICATIONS (leave blank if not applicable)

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INDICATIONS RELATING TO A DEPOSITED MICROORGANISM OR OTHER BIOLOGICAL MATERIAL

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description at Table 6.

B. IDENTIFICATION OF DEPOSIT

Further deposits are identified on an additional sheet ☒

Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)
10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

June 18, 1999

Accession Number

PTA-253

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL**

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description at Table 6.

B. IDENTIFICATION OF DEPOSIT

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Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)

10801 University Boulevard

Manassas, Virginia 20110-2209

United States of America

Date of deposit

December 22, 1999

Accession Number

PTA-1081

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL**

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description at page 14, paragraph 38.

B. IDENTIFICATION OF DEPOSIT

Further deposits are identified on an additional sheet ☒

Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)
10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

October 5, 2000

Accession Number

PTA-2574

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL**

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description at page 14, paragraph 38.

B. IDENTIFICATION OF DEPOSIT

Further deposits are identified on an additional sheet ☒

Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)

10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

October 5, 2000

Accession Number

PTA-2575

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
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B. IDENTIFICATION OF DEPOSIT

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Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)
10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

January 5, 2001

Accession Number

(HGS reference code TS-1)

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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B. IDENTIFICATION OF DEPOSIT

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10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

January 5, 2001

(HGS reference code TS-2)

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Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
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(PCT Rule 13bis)

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B. IDENTIFICATION OF DEPOSIT

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Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)

10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

January 5, 2001

Accession Number

(HGS reference code AC-1)

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

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**INDICATIONS RELATING TO A DEPOSITED MICROORGANISM
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Name of depositary institution: American Type Culture Collection

Address of depositary institution (including postal code and country)

10801 University Boulevard
Manassas, Virginia 20110-2209
United States of America

Date of deposit

January 5, 2001

Accession Number

(HGS reference code AC-2)

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

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D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

Europe

In respect of those designations in which a European Patent is sought a sample of the deposited microorganism will be made available until the publication of the mention of the grant of the European patent or until the date on which the application has been refused or withdrawn or is deemed to be withdrawn, only by the issue of such a sample to an expert nominated by the person requesting the sample (Rule 28(4) EPC).

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ATCC Deposit No.: 209059, 209060, 209061, 209062, 209063, 209064, 209065, 209066, 209067, 209068, 209069, 209579, 209578, 203067, 203068, 203609, 203610, 203485, PTA-252, PTA-253, PTA-1081, PTA-2574, PTA-2575, TS-1, TS-2, AC-1, AC-2

CANADA

The applicant requests that, until either a Canadian patent has been issued on the basis of an application or the application has been refused, or is abandoned and no longer subject to reinstatement, or is withdrawn, the Commissioner of Patents only authorizes the furnishing of a sample of the deposited biological material referred to in the application to an independent expert nominated by the Commissioner, the applicant must, by a written statement, inform the International Bureau accordingly before completion of technical preparations for publication of the international application.

NORWAY

The applicant hereby requests that the application has been laid open to public inspection (by the Norwegian Patent Office), or has been finally decided upon by the Norwegian Patent Office without having been laid open to inspection, the furnishing of a sample shall only be effected to an expert in the art. The request to this effect shall be filed by the applicant with the Norwegian Patent Office not later than at the time when the application is made available to the public under Sections 22 and 33(3) of the Norwegian Patents Act. If such a request has been filed by the applicant, any request made by a third party for the furnishing of a sample shall indicate the expert to be used. That expert may be any person entered on the list of recognized experts drawn up by the Norwegian Patent Office or any person approved by the applicant in the individual case.

AUSTRALIA

The applicant hereby gives notice that the furnishing of a sample of a microorganism shall only be effected prior to the grant of a patent, or prior to the lapsing, refusal or withdrawal of the application, to a person who is a skilled addressee without an interest in the invention (Regulation 3.25(3) of the Australian Patents Regulations).

FINLAND

The applicant hereby requests that, until the application has been laid open to public inspection (by the National Board of Patents and Regulations), or has been finally decided upon by the National Board of Patents and Registration without having been laid open to public inspection, the furnishing of a sample shall only be effected to an expert in the art.

ATCC Deposit No.: 209059, 209060, 209061, 209062, 209063, 209064, 209065, 209066, 209067, 209068, 209069, 209579, 209578, 203067, 203068, 203609, 203610, 203485, PTA-252, PTA-253, PTA-1081, PTA-2574, PTA-2575, TS-1, TS-2, AC-1, AC-2

UNITED KINGDOM

The applicant hereby requests that the furnishing of a sample of a microorganism shall only be made available to an expert. The request to this effect must be filed by the applicant with the International Bureau before the completion of the technical preparations for the international publication of the application.

DENMARK

The applicant hereby requests that, until the application has been laid open to public inspection (by the Danish Patent Office), or has been finally decided upon by the Danish Patent office without having been laid open to public inspection, the furnishing of a sample shall only be effected to an expert in the art. The request to this effect shall be filed by the applicant with the Danish Patent Office not later than at the time when the application is made available to the public under Sections 22 and 33(3) of the Danish Patents Act. If such a request has been filed by the applicant, any request made by a third party for the furnishing of a sample shall indicate the expert to be used. That expert may be any person entered on a list of recognized experts drawn up by the Danish Patent Office or any person by the applicant in the individual case.

SWEDEN

The applicant hereby requests that, until the application has been laid open to public inspection (by the Swedish Patent Office), or has been finally decided upon by the Swedish Patent Office without having been laid open to public inspection, the furnishing of a sample shall only be effected to an expert in the art. The request to this effect shall be filed by the applicant with the International Bureau before the expiration of 16 months from the priority date (preferably on the Form PCT/RO/134 reproduced in annex Z of Volume I of the PCT Applicant's Guide). If such a request has been filed by the applicant any request made by a third party for the furnishing of a sample shall indicate the expert to be used. That expert may be any person entered on a list of recognized experts drawn up by the Swedish Patent Office or any person approved by a applicant in the individual case.

NETHERLANDS

The applicant hereby requests that until the date of a grant of a Netherlands patent or until the date on which the application is refused or withdrawn or lapsed, the microorganism shall be made available as provided in the 31F(1) of the Patent Rules only by the issue of a sample to an expert. The request to this effect must be furnished by the applicant with the Netherlands Industrial Property Office before the date on which the application is made available to the public under Section 22C or Section 25 of the Patents Act of the Kingdom of the Netherlands, whichever of the two dates occurs earlier.